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10/617,334	07/10/2003	Michael R. Hayden	760050-91	5209

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CARELLA, BYRNE, BAIN, GILFILLAN, CECCHI,
STEWART & OLSTEIN
6 Becker Farm Road
Roseland, NJ 07068

EXAMINER	
STEADMAN, DAVID J	

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1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/617,334	HAYDEN ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27,29-40,46-61 and 63-68* is/are pending in the application.

4a) Of the above claim(s) *1-23,29-40,46-48 and 50-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-27,49,57-61 and 63-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/21/08, 3/6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1-27, 29-40, 46-61, and 63-68 are pending in the application.

[2] Applicant's amendment to the claims, filed on 4/21/08, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Receipt of a terminal disclaimer, filed on 4/21/08, is acknowledged.

[4] Receipt of an information disclosure statement, filed on 4/21/08, is acknowledged.

[5] Applicant's arguments filed on 4/21/08 in response to the Office action mailed on 10/26/07 have been fully considered and are deemed to be persuasive to overcome some of the objections and/or rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[6] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Election/Restriction

[7] Claims 1-23, 29-40, 46-48, and 50-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/6/2006.

[8] Claims 49, 58, and 60 are being examined only to the extent the claims read on the elected subject matter.

Information Disclosure Statement

[9] All references cited in the information disclosure statement filed on 4/21/08 have been considered by the examiner. A copy of Forms PTO-1449 is attached to the instant Office action.

[10] Applicant's request (p. 10 of the instant remarks) regarding the information disclosure statement filed on 3/6/06 is acknowledged. A copy of Forms PT-1449 are attached to the instant Office action.

Claim Objection

[11] Applicant is advised that should claim 67 be found allowable, claim 68 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112, Second Paragraph

[12] The rejection of claims 24-27, 49, and 57-66 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendment to claim 24 to recite an active method step, namely "administering to said human..."

Claim Rejections - 35 USC § 101

[13] The rejection of claims 24-27, 49, and 57-66 under 35 U.S.C. 101 as failing to set forth any steps involved in the process is withdrawn in view of applicant's amendment to claim 24 to recite an active method step, namely "administering to said human..."

Claim Rejections - 35 USC § 112, First Paragraph

[14] The written description rejection of claims 24-27, 49, 57-61, and 63-66 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See particularly paragraph 14 beginning at p. 5 of the 10/26/07 Office action. Newly added claims 67-68 are included in the instant rejection and thus, claims 24-27, 49, 57-61, and 63-68 are rejected herein.

RESPONSE TO ARGUMENT: Beginning at p. 12, middle of the instant remarks, applicant argues:

> The Examiner contends *inter alia* that the claims do not recite what is actually treated by increasing ABC1 lipid transport activity (office action at page 6, lines 1-7) and that the claim is not limited to treatment by administering a compound (office action at page 10, lines 5-6). In response, Applicants have amended claim 24 (and thus all of the dependent claims) to recite that the claimed method is specifically drawn to increasing HDL levels in a patient by increasing ABC1 activity and is thus far more particular in reciting the condition to be addressed. As Applicants have related in a previous paper, the link between HDL and cardiovascular disease was demonstrated in the application. In addition, the amended claims also recite that increased HDL is achieved by administering an agent that increases ABC1 lipid transport activity. As noted previously, the reference in the application to modulating ABC1

activity and HDL levels is intended to be alternative designations and not as different processes that can be separately modulated.

Applicant's argument is not found persuasive. The claim 24 amendment is acknowledged. However, the examiner maintains the position that the specification fails to show that applicant was in possession of the claimed invention.

As noted in a prior Office action, in providing guidance for evaluating a claimed invention for adequate written description, MPEP 2163.II.A.1 states, "the examiner should determine what the claim as a whole covers. "Claim construction is an essential part of the examination process. Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description. See, e.g., *In re Morris*, 127 F.3d 1048, 1053-54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997)."

Claim 24 is drawn to a method of treating increasing plasma HDL-C in a human by administering a genus of agents that increase ABC1 lipid transport activity by at least 10% in cells of the human. The genus of agents is unlimited with respect to type of and structure of the species of agents, *e.g.,* small molecule organic compounds, nucleic acids including antisense compounds, and polypeptides including antibodies. Also, the genus of agents is unlimited with respect to function, including those agents that increase ABC1 lipid transport activity by a direct effect, *e.g.,* a compound that binds to the active site of ABC1 or an indirect effect, *e.g.,* a compound that alters function of a polypeptide that regulates ABC1 activity.

For claims drawn to a genus, MPEP § 2163 states the written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. Sufficient description to show possession of such a genus "may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. *See University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

As noted above, the genus of recited agents encompasses widely variant species with respect to both type/structure and function. In remarks provided addressing the rejection under 35 U.S.C. 112, second paragraph, applicant asserts, "Applicants

recite numerous agents that modulate ABC1 activity, Including increasing said activity (see, for example, the application at page 53, lines 7-27)". The disclosure at p. 53, lines 7-27 appears to be related to discussing compounds that activate PPARα and *may* or *could* have an effect on ABC1 expression. According to the disclosure "Compounds which alter activity of any of the PPARs...*may* have an effect on ABC1 expression and thereby *could* affect HDL levels...Drugs that modulate PPARs *may* therefore have an important effect on modulating lipid levels…and altering CAD risk. This effect *could* be achieved through modulation of ABC1 gene expression…Drugs with combined PPARα and PPARγ agonist activity or PPARα and PPARγ agonists given in combination for example, *may* increase HDL levels even more" (emphasis added). Thus, while applicant argues that modulators of ABC1 activity to increase HDL-C levels are disclosed, this disclosure appears to be a suggestion of what may or could happen. A skilled artisan would recognize such a suggestion as more of a "wish or plan for obtaining the claimed chemical invention", rather than showing possession of the claimed invention. For example, while the compound *may* or *could* enhance ABC1 mRNA expression, the prior art recognizes that there is no way to predict that enhanced mRNA levels will result in a corresponding increase in protein levels. As noted in *Rochester,* "As we held in Lilly, "[a]n adequate written description of a DNA . . . 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." 119 F.3d at 1566 (quoting Fiers, 984 F.2d at 1171)".

Even assuming *arguendo* a skilled artisan would recognize this disclosure as teaching that the disclosed PPARα modulating agents have the effect of increasing ABC1 expression, there is no evidence that the compounds have the ability to increase ABC1 lipid transport activity. Even assuming *arguendo* the compounds have the ability to increase ABC1 lipid transport activity, there is no evidence of record that the disclosed PPARα modulating agents achieve the required "at least 10%", "at least 25%", or "at least 50%" increase in ABC1 lipid transport and the "at least 25%" or "at least 50%" increase in plasma HDL-C in cells of a human. Even assuming *arguendo* a skilled artisan would recognize this disclosure as providing representative species of compounds that increase ABC1 lipid transport activity by the required level of "at least 10%", these representative compounds would fail to reflect the structural and functional variation among the species of the genus of recited compounds. As noted in the prior Office action, even after the time of the invention, there is a high level of unpredictability regarding those treatment methods targeting ABCA1 as evidenced by the teachings of the reference of Nofer et al., which discloses that a therapeutic for targeting ABCA1 in the treatment of coronary heart disease "has not yet been fulfilled" (Nofer et al. *Cell Mol Life Sci* 62:2150-2160, 2005; p. 2156, right column, bottom). According to MPEP 2163.II.3.(a).ii), "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when … the evidence indicates ordinary

artisans could not predict the operability in the invention of any species other than the one disclosed." *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004). Since the specification and prior art fail to disclose even a single representative species of the claimed genus of methods and because there is unpredictability in the art of treating coronary heart disease via ABCA1, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

At least for the reasons of record and those set forth above, the specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph.

[15] The new matter rejection of claims 24-27, 49, 57-61, and 63-66 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See particularly paragraph 15 beginning at p. 9 of the 10/26/07 Office action. Newly added claims 67-68 are included in the instant rejection and thus, claims 24-27, 49, 57-61, and 63-68 are rejected herein.

RESPONSE TO ARGUMENT: Beginning at p. 12, middle of the instant remarks, applicant argues:

> The Examiner contends *inter alia* that the claims do not recite what is actually treated by increasing ABC1 lipid transport activity (office action at page 6, lines 1-7) and that the claim is not limited to treatment by administering a compound (office action at page 10, lines 5-6). In response, Applicants have amended claim 24 (and thus all of the dependent claims) to recite that the claimed method is specifically drawn to increasing HDL levels in a patient by increasing ABC1 activity and is thus far more particular in reciting the condition to be addressed. As

> Applicants have related in a previous paper, the link between HDL and cardiovascular disease was demonstrated in the application. In addition, the amended claims also recite that increased HDL is achieved by administering an agent that increases ABC1 lipid transport activity. As noted previously, the reference in the application to modulating ABC1 activity and HDL levels is intended to be alternative designations and not as different processes that can be separately modulated.

Applicant's argument is not found persuasive. As noted in the prior Office action, the disclosure relied upon by applicant to show support for the claim limitations, *i.e.*, p. 14, lines 18-22 of the specification, appears to be related to providing descriptive support for a "compound" that modifies cholesterol or ABC1 activity by at least 10%, more preferably by at least 25%, and most preferably by at least 50%. In this case, the claim recites an "agent", not a "compound" and the two terms' meanings are not necessarily of equal scope. As such, the disclosure at p. 14, lines 18-22 would not appear to provide explicit, implicit, or inherent disclosure to support the noted limitations. Applicant is invited to show support for the limitations of claims 24-27, 49, 57-61, and 63-68.

[16] The enablement rejection of claims 24-27, 49, 57-61, and 63-66 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. The rejection was fully explained in a prior Office action. See particularly paragraph 16 beginning at p. 10 of the 10/26/07 Office action. Newly added claims 67-68 are included in the instant rejection and thus, claims 24-27, 49, 57-61, and 63-68 are rejected herein.

RESPONSE TO ARGUMENT: Beginning at p. 12, middle of the instant remarks, applicant argues:

> Applicants have amended the claims to better identify the contemplated invention (e.g., clearly reciting that ABC1 transporter activity is to be increased in amended claim 24 as the basis for increasing HDL levels by administration of agents, many of which are recited in the specification (see above citations to the application). In addition, Applicants have disclosed agents useful in increasing ABC1 lipid transport activity (e.g., ABC1 polypeptides and fragments in the previous response and other agents cited hereinabove).
>
> Further, the Examiner notes the absence of working examples to support a claim to increasing ABC1 activity in a patient (see Office Action at page 13). In response, Applicants note that working examples are not essential to show enablement of a claimed invention. Instead, Applicants have provided examples of the effects of reduced ABC1 activity in patients and the concomitant effects on HDL (see the citations to the specification above) and have disclosed agents that increase ABC1 activity. Unless such link cannot possibly be maintained, Applicants contend that the link between ABC1 activity in cells, such as fibroblasts, of a patient and HDL levels has been shown and that increase in ABC1 activity should have the expected effect on HDL levels. In addition, Applicants disclose compounds that increase ABC1 activity.

Applicant's argument is not found persuasive. The claim 24 amendment is acknowledged. However, the examiner maintains the position that the specification fails to enable the claimed invention.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue." *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8

USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

(A) The breadth of the claims: According to MPEP 2164.04, "[b]efore any analysis of enablement can occur, it is necessary for the examiner to construe the claims…and explicitly set forth the scope of the claim when writing an Office action." Also, MPEP 2164.08 states, "[a]ll questions of enablement are evaluated against the claimed subject matter. The focus of the examination inquiry is whether everything within the scope of the claim is enabled. Accordingly, the first analytical step requires that the examiner determine exactly what subject matter is encompassed by the claims…claims are to be given their broadest reasonable interpretation that is consistent with the specification."

As noted above, claim 24 is drawn to a method of treating increasing plasma HDL-C in a human by administering a genus of agents that increase ABC1 lipid transport activity by at least 10% in cells of the human. The genus of agents is unlimited with respect to type of and structure of the species of agents, *e.g.*, small molecule organic compounds, nucleic acids including antisense compounds, and polypeptides including antibodies. Also, the genus of agents is unlimited with respect to function,

including those agents that increase ABC1 lipid transport activity by a direct effect, *e.g.*, a compound that binds to the active site of ABC1 or an indirect effect, *e.g.*, a compound that alters function of a polypeptide that regulates ABC1 activity.

(C) The state of the prior art; (D) The level of one of ordinary skill; and (E) The level of predictability in the art: According to MPEP 2164.03, "...what is known in the art provides evidence as to the question of predictability." At the time of the invention, neither the specification nor the prior art discloses a method for providing any treatment in a human having or at risk of developing a cardiovascular disease by increasing by at least 10%, 25%, or 50% the level of ABC1 lipid transport activity in the human. Even *after* the time of the invention the art recognizes that a therapeutic targeting ABCA1 for the treatment of coronary heart disease "has not yet been fulfilled" (Nofer et al. *Cell Mol Life Sci* 62:2150-2160, 2005; p. 2156, right column, bottom), providing evidence of a high level of unpredictability for practicing the claimed method. While Nofer et al. acknowledges that "such treatments may be on the horizon," the reference also acknowledges that at least one potential therapy, namely LXR agonists, may cause gene changes that are detrimental (p. 2157, left column, top). Applicant argues compounds that increase ABC1 activity are disclosed in the specification and in remarks provided addressing the rejection under 35 U.S.C. 112, second paragraph, applicant asserts, "Applicants recite numerous agents that modulate ABC1 activity, Including increasing said activity (see, for example, the application at page 53, lines 7-27)". The disclosure at p. 53, lines 7-27 appears to be related to discussing compounds that activate PPARα and according to the disclosure "Compounds which alter activity of any

of the PPARs...*may* have an effect on ABC1 expression and thereby *could* affect HDL levels...Drugs that modulate PPARs *may* therefore have an important effect on modulating lipid levels...and altering CAD risk. This effect *could* be achieved through modulation of ABC1 gene expression...Drugs with combined PPARα and PPARγ agonist activity or PPARα and PPARγ agonists given in combination for example, *may* increase HDL levels even more" (emphasis added). Thus, while applicant argues that modulators of ABC1 activity to increase HDL-C levels are disclosed, this disclosure appears to be only a suggestion of what may or could happen. For example, while the compound *may* or *could* enhance ABC1 mRNA expression, the prior art recognizes that there is no way to predict that enhanced mRNA levels will result in a corresponding increase in protein levels. Even assuming *arguendo* ABC1 mRNA positively correlated with the levels of ABC1 protein, there is no indication that increased ABC1 protein levels correlate with increased ABC1 lipid transport activity. The post-filing art acknowledges that a compound as ubiquitous as aspirin increases ABC1 expression (see Vinals et al. *Cardiovasc. Res.* 66:141-149, 2005, particularly p. 147, Figure 8), there is no indication that a human taking aspirin would achieve an increase in ABC1 lipid transport activity by at least 10%.

In this case, the specification and/or prior art fail to set forth even a single method for achieving an increase in ABC1 lipid transport activity of at least 10% in a human.

(F) The amount of direction provided by the inventor and (G) The existence of working examples: The specification fails to disclose even a single working example of the claimed method that achieves an increase of at least 10% of ABC1 lipid transport

activity in an affected human as encompassed by the claims. While it is acknowledged that MPEP 2164.02 states, "[c]ompliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed," this same section of MPEP makes clear that "[l]ack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art." As such, lack of a working example has been considered along with the other Factors of *In re Wands* in the enablement analysis.

While the specification discloses general methods for, *e.g.*, isolating compounds that may achieve the desired increase in ABCA1 lipid transport activity, such guidance amounts to a trial and error research plan without providing any specific guidance regarding those compounds that are likely to be successful for practicing the claimed method. The specification fails to provide guidance regarding, *e.g.*, production of the polypeptide and the associated potential for antigenic effects in a human, whether or not the polypeptide has lipid transport activity without further processing or post-translational modification, stability/turnover of the polypeptide, formulation of the polypeptide for administration, routes of administration, and dosage level required to achieve increased ABC1 lipid transport activity by at least 10%, 25%, or 50% in a human, which are all relevant considerations for protein therapeutics. In this case, in view of the high level of unpredictability and lack of guidance provided in the specification, a skilled artisan would have no expectation that such a method can be achieved.

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: While methods of treatment of a cardiovascular disease were known in the art at the time of the invention, it was not routine to experiment to identify *all* agents for increasing by at least 10%, 25%, or 50% the ABCA1 lipid transport activity in a human.

In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the claimed invention.

Double Patenting

[17] It is noted that applicant's instant filed terminal disclaimer listing US application No. 10/744,465 is duplicative in view of the terminal disclaimer filed on 11/14/06 listing the same US application.

[18] Applicant is reminded that the examiner has made an earnest attempt to identify those patents and/or co-pending applications for purposes of rejecting or provisionally rejecting the claims for double patenting. However, it is noted that numerous co-pending applications have been filed and/or continue to be filed, and/or patents have issued disclosing subject matter that is related to the instant application. In the interest of compact prosecution, the examiner requests that: 1) applicants identify any patent(s) and/or co-pending application(s) that claim(s) subject matter that may necessitate a double patenting rejection, an obviousness-type double patenting rejection, a

provisional double patenting rejection, or a provisional obviousness-type double patenting rejection; 2) identify the claims of the patents and/or co-pending applications that claim identical or similar subject matter; 3) identify the corresponding claims of the instant application, and 4) take the appropriate action, *e.g.,* cancel claims to preempt a statutory double patenting rejection and/or file a terminal disclaimer to preempt an obvious-type double patenting rejection or provisional rejection. Applicants' cooperation in following steps 1) to 4) above is appreciated as this will allow the examiner to focus on more substantive issues in the examination of the instant application.

Conclusion

[19] Status of the claims:

- Claims 1-27, 29-40, 46-61, and 63-68 are pending.
- Claims 1-23, 29-40, 46-48, and 50-56 are withdrawn from consideration.
- Claims 24-27, 49, 57-61, and 63-68 are rejected.
- No claim is in condition for allowance.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/
David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656